## 510(k) SUMMARY

*[As required by 21 CFR 807.92(c)]*

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|---|---|
| **Date Prepared** | 15 April 2014 |
| **Submitter Name** | Nicole Gaddi |
| **Official Contact** | Mr. Jim Cassi<br>Vice President - Quality Assurance Americas<br>9001 Spectrum Center Blvd<br>San Diego CA 92123 USA<br>Tel: (858) 836 6081 |
| **Device Trade Name** | ResScan |
| **Device Common Name** | Continuous Ventilator |
| **Classification/s & Classification Name/s** | 21 CFR 868.5905, 73 BZD (Class II)<br>Non continuous ventilator (IPPB)<br>21 CFR 868.5895, 73 MNS (Class II)<br>Continuous Ventilator<br>21 CFR 868.5895, 73 MNT (Class II)<br>Continuous Ventilator<br>21 CFR 868.5895, 73 CBK (Class II)<br>Ventilator, continuous, facility use |
| **Legally Marketed Predicate Device** | ResScan (K113815) |
| **Reason for Submission** | New Device |

### Indication for Use

ResScan is intended to augment the standard follow-up care of patients by providing transfer of machine and therapeutic information. This includes the ability to remotely change settings in non-life support devices only.
It is intended to be used by Clinicians in conjunction with ResMed compatible therapy devices, using ResMed's proprietary communications protocol.

### Device Description

The performance and functional characteristics of ResScan includes all the user friendly features of the predicate device.
ResScan allows the clinician to:

- Download and view patient and machine data from ResMed flow generators
- Store patient details
- Set machine parameters (Using Removal Media or PC direct connection), non-life support devices only.
- Create and print reports
- Uses Removal Media or PC direct connection as the interface between the flow generator and ResScan
- Support for Data Card Reader

**Substantial Equivalence**

The new device has the following similarities to the previously cleared predicate device.

- Similar intended use
- Same operating principle
- Same technologies
- Same manufacturing process

Design and Verification activities were performed on ResScan as a result of the risk analysis and design requirements. Verification testing included end-to-end testing to confirm that settings were successfully transferred between the flow generator and ResScan, and data captured by the flow generator was sent to ResScan. All tests confirmed the product met the predetermined acceptance criteria. ResMed has determined that the new device is substantially equivalent to the predicate device and any changes do not raise new questions of safety and effectiveness when used for patient compliance management as an adjunct with ResMed flow generators. The new device complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Off-the-Shelf Software Use in Medical Devices (September 9,1999)

| Feature | ResScan predicate(K113815) | ResScan (modified) | Comments |
|---|---|---|---|
| Intended Use | ResScan™ is intended to augment the standard follow-up care of patients by providing transfer of machine and therapeutic information, including the ability to remotely change settings.<br><br>It is intended to be used by Clinicians in conjunction with ResMed compatible flow generators, using ResMed's proprietary communications protocol. | ResScan™ is intended to augment the standard follow-up care of patients by providing transfer of machine and therapeutic information. This includes the ability to remotely change settings in non-life support devices only.<br><br>It is intended to be used by Clinicians in conjunction with ResMed compatible therapy devices, using ResMed's proprietary communications protocol. | Equivalent:<br>*Remote setting change functionality is not applicable to ResMed CBK therapy devices.* |
| Location of use | • Hospital | • Hospital | Equivalent |
| Functionality | • Display of therapy data<br>• Generate reports<br>• Settings management<br>• Patient management | • Display of therapy data<br>• Generate reports<br>• Settings management<br>• Patient management | Equivalent:<br>*Remote setting change functionality only applies to non-life support devices* |
| Compatible flow generators | • Resmed compatible therapy devices (73 BZD, 73 MNS and 73 MNT ) | • Resmed compatible therapy devices (73 BZD, 73 MNS, 73 MNT and 73 CBK ) | Equivalent:<br>*Remote setting change functionality only applies to non-life support devices* |

| Feature | ResScan predicate(K113815) | ResScan (modified) | Comments |
|---|---|---|---|
| Communication medium | • Serial connection<br>• Removable medium | • Serial connection<br>• Removable medium | Equivalent:<br>*Serial connection only applies to non-life support devices* |
| Patient information | • Mask Leak<br>• AHI<br>• Pressure<br>• Minute Ventilation<br>• Respiratory rate | • Mask Leak<br>• AHI<br>• Pressure<br>• Minute Ventilation<br>• Respiratory rate | Equivalent |
| Changeable settings | • Start Pressure<br>• Set Pressure<br>• Ramp time<br>• Setting time | • Start Pressure<br>• Set Pressure<br>• Ramp time<br>• Setting time | Equivalent:<br>*Remote setting change functionality only applies to non-life support devices* |

**Non-Clinical Testing**

Design and non-clinical verification activities were performed on ResScan as a result of the updated risk analysis and design requirements. Verification testing included End-to-End bench testing to verify that ResScan, using only Removable Media, can receive patient usage, device settings, therapy summary data, detailed signal data and device log information from the flow generator (data). All tests confirmed the product met the predetermined acceptance criteria. ResMed has determined that the new version of ResScan is substantially equivalent to the predicate device, ResScan (K113815).

ResScan met the predetermined pass/fail criteria as defined in the ResScan System Verification Report.

**Clinical Testing**

Clinical testing was not deemed necessary as identified in the Risk Analysis, as ResScan only obtains patient and machine information from therapeutic devices for which clinical trials have already been conducted, or compared with previous predicate comparison test results. Accordingly no clinical testing is required.

**Summary of additional features from the ResScan (K113815)**

- ResMed compatible therapy devices include, e.g. VPAP Bilevel devices (73 MNS).
- Life support therapy device (73 CBK).
- Display/reporting of multiple therapy programs for life support therapy devices.
- Display/reporting of additional modes such as ASVAuto, ACV, PACV, V-SIMV, P-SIMV, & PS.
- Support for Windows Remote Desktop Environments.

The inclusion of these features has been assessed within the risk analysis and no additional safety risks have been found as a result of the inclusion of these features.

**Conclusion**

The modified ResScan is as safe and as effective as the predicate device, ResScan (K113815) and is deemed substantially equivalent to the predicate device, ResScan (K113815).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 16, 2014

Resmed Corporation
Mr. Jim Cassi
Vice President, Quality Assurance Americas
9001 Spectrum Center Blvd.
San Diego, CA 92123

Re: K140054
Trade/Device Name: ResScan
Regulation Number: 21 CFR 868.5905
Regulation Name: Non-continuous Ventilator
Regulatory Class: II
Product Code: BZD, MNS, MNT, CBK
Dated: April 16, 2014
Received: April 18, 2014

Dear Mr. Cassi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Acting Director
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Respiratory, Infection Control and
Dental Devices
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Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*
K140054

Device Name
ResScan

Indications for Use *(Describe)*

ResScan is intended to augment the standard follow-up care of patients by providing transfer of machine and therapeutic information. This includes the ability to remotely change settings in non-life support devices only.
It is intended to be used by Clinicians in conjunction with ResMed compatible therapy devices, using ResMed's proprietary communications protocol.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA
Anya C. Harry -S
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